



Update on KoCVAM Activities

(July 2010~June 2011)

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Relocation of NIFDS/KFDA



Osong Health Technology Administration Complex

1. Korea Food and Drug Administration (KFDA)
2. National Institute of Food and Drug Safety Evaluation (NIFDS)
3. Korea Centers for Disease Control and Prevention (KCDC)
4. Korea National Institute of Health (KNIH)
5. Korea Health Industry Development Institute (KHIDI)
6. Korea Human Resource Development Institute for Health and Welfare (KHRDI)



Relocation of NIFDS/KFDA

- NIFDS/KFDA have been relocated to Osong Health Technology Administration Complex (November 2010~March 2011)
 - Laboratory animal, national reference standard, various equipments, radioisotope, narcotics, etc.
- Validation of laboratories and animal facilities has been completed



Signing Ceremony of Modified ICATM MoC

- **When**
 - March 8th, 2011
- **Where**
 - Washington Convention Center, U.S
- **Objective**
 - Support the membership of KoCVAM in the ICATM
- **Participants**
 - Dr. Linda Birnbaum (NIEHS/NTP)
 - Mr. Mike Inskip (Health Canada)
 - Dr. Joachim Kreysa (ECVAM)
 - Dr. Yasuo Ohno (NIHS)
 - Dr. Seung Hee Kim (KFDA/NIFDS)






International Collaboration




International Validation Study – *In Vitro* Endocrine Disruptor Screening Test

- KFDA laboratory participated in NICEATM/ICCVAM-led international validation study
 - Test system
 - CCI MCF-7 cell proliferation assays
 - Current status
 - Phase I ~ Phase III testing completed (2010.03~2010.12)
 - Final report submitted to NICEATM/ICCVAM (2010.12)
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International Validation Study – *In Vitro* Genotoxicity Test

- Korean CRO (Korea Institute of Toxicology) participated in JaCVAM-led international validation study
 - Test system
 - *In vitro* alkaline Comet assay
 - Current status
 - Phase III pre-validation testing on 4 coded chemicals completed (2010.09~2011.02)
 - Data submitted to JaCVAM (2011.02)
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On Going Exploratory Study – Skin Sensitization (BrdU:LLNA-FC)

- Future study
 - Pre-validation study using coded chemicals according to performance standard in OECD TG 429
 - Intra-laboratory study in Korea
 - Inter-laboratory study in Korea





On Going Exploratory Study – Eye Irritation (BCOP assay)

- Objective
 - Assess usefulness of histopathologic and histomorphometric evaluation as additional endpoints of BCOP assay
 - Test system
 - Bovine Corneal Opacity and Permeability assay (BCOP assay)
 - Assessment
 - Scoring histopathologic changes in cornea
 - Calculating a ratio of damaged layer to each layer in cornea
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On Going Exploratory Study – Eye Irritation (BCOP assay)

- Current status
 - Testing on 14 test chemicals completed

Class	Chemical name
Alcohol	Glycerol; 2-Ethyl-1-hexanol; 2,4-pentannediol; Ethanol
Ketone	Methyl ethyl ketone; Ethyl-2-methylacetoacetate
Carboxylic acid	Dibenzoyl-L tartaric acid; Trichloroacetic acid(30%)
Inorganic, Onium	Benzalkonium chloride(5%), Ammonium nitrate
Acyl halide and Acyclic hydrocarbon	2,6-Dichlorobenzoyl chloride, n-Hexane
Inorganic, Heterocycle	Imidazole
Amine	Chlorhexidine

- Histopathologic peer review underway on tested bovine cornea



On Going Exploratory Study – Eye Irritation (BCOP assay)

- Future study
 - Plan to publish a paper which will include our test results
 - Suggested BCOP assay (based on OECD TG 437) for a domestic guideline adopted to assess safety of cosmetics





KoCVAM Activities

Publication of Korean Guideline

- Handbook on the validation of alternative methods in Korea (based on OECD series on testing and assessment No. 34)



International Colloquium

- **When**
 - August 26th, 2010
- **Where**
 - Korea Food and Drug Administration, Seoul, Korea
- **Program**
 - ECVAM: organisation, validation, innovation and communication
 - Proposal for operation of KoCVAM and advance in animal alternative tests in Korea
 - Discussion between KoCVAM and ECVAM on the direction of future collaboration for validation studies



2nd International Symposium

- When
 - August 27th, 2010
- Where
 - Kyung-Hee University, Suwon, Korea
- Program
 - Global efforts for the validation of animal alternative tests
 - Special lectures on alternative test methods
 - Current efforts of CROs on reduction of animal use in Korea
 - Regulatory perspective on animal alternative test methods



Training Workshop on Alternative Test Methods

- When
 - August 28th, 2010
- Where
 - Kyung-Hee University, Suwon, Korea
- Program
 - Lecture
 - International trends of animal alternative test methods
 - Training
 - Skin sensitization test: BrdU:LLNA-ELISA
 - Skin irritation test: Human reconstructed skin model
 - Eye irritation test: BCOP assay



KoCVAM 2nd Workshop

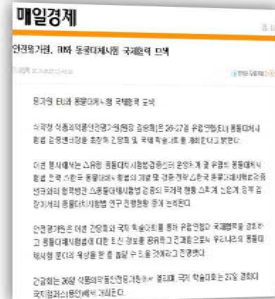
- When
 - May 27th, 2011
- Where
 - Gyeonggi Bio-Center, Suwon, Korea
- Title
 - Understanding of international validation study
- Program
 - KoCVAM `s activities and international cooperation
 - Introduction of handbook on the validation of alternative methods in Korea
 - Introduction of international validation participation in Korea
 - Alternative test for biologics in KFDA
 - Skin sensitisation: Experience during 20 years of validation



Promotional Activity of KoCVAM



- KoCVAM's participation ICATM expected (July 13th, 2010)



- Hold a international symposium with KSAEA (August 25th, 2010)




- KoCVAM, Signing modified ICATM MoC (March 9th, 2011)



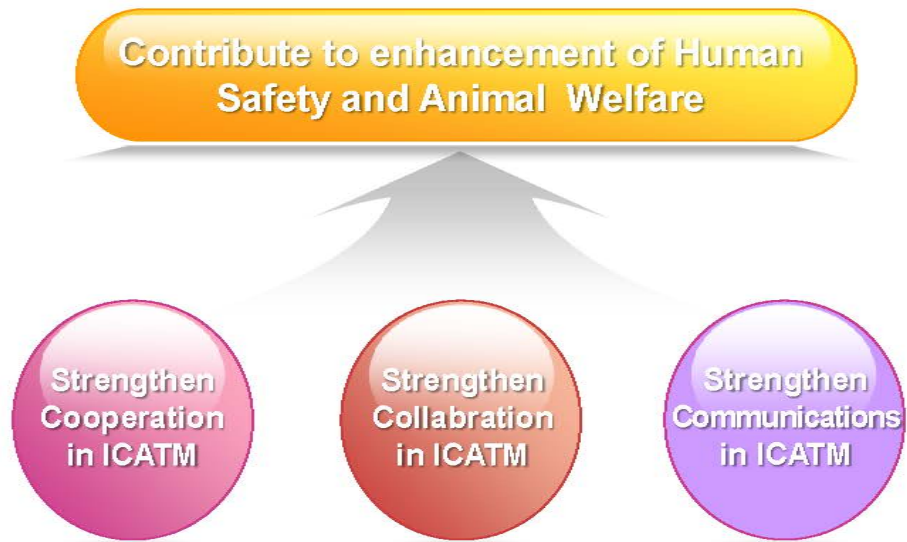
- Hold KoCVAM 2nd Workshop (May 26th, 2011)



Future Activities

- 3rd international symposium
 - When: July 8th, 2011
 - Where: Hoseo University, Korea
 - Program
 - Current trend of alternative test methods in Japan
 - Current trend of alternative test methods in China
 - *In-Silico* AMDA models for assessment of developmental neurotoxicants. etc.
 - 3rd training workshop on alternative test methods (November, 2011)
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KoCVAM Contribution to ICATM



Thank you for your attention



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